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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,812	04/16/2004	Corey S. Goodman	18941H-002911US	1573

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,812	GOODMAN ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 10-19, drawn to an antibody to a polypeptide of SEQ ID NO: 8, classified in class 530, subclass 387.1, for example.

II. Claims 20-22, drawn to an antibody to a polypeptide of SEQ ID NO: 10, classified in class 530, subclass 387.1, for example.

III. Claim 23, in so far as it is drawn to an antibody to a polypeptide of SEQ ID NO: 2, classified in class 530, subclass 387.1, for example.

IV. Claim 23, in so far as it is drawn to an antibody to a polypeptide of SEQ ID NO: 4, classified in class 530, subclass 387.1, for example.

V. Claim 23, in so far as it is drawn to an antibody to a polypeptide of SEQ ID NO: 6, classified in class 530, subclass 387.1, for example.

VI. Claim 23, in so far as it is drawn to an antibody to a polypeptide of SEQ ID NO: 12, classified in class 530, subclass 387.1, for example.

VII. Claims 24-26, in so far as they are drawn to a polypeptide of SEQ ID NO: 8, classified in class 530, subclass 350, for example.

VIII. Claims 24-26, in so far as they are drawn to a polypeptide of SEQ ID NO: 10, classified in class 530, subclass 350, for example.

IX. Claim 27, in so far as it is drawn to a method of using a polypeptide of SEQ ID NO: 8, classified in class 435, subclass 7.1, for example.

X. Claim 27, in so far as it is drawn to a method of using a polypeptide of SEQ ID NO: 10, classified in class 435, subclass 7.1, for example.

XI. Claim 28, in so far as it is drawn to a polynucleotide encoding a polypeptide of SEQ ID NO: 8, classified in class 435, subclass 69.1, for example.

XII. Claim 28, in so far as it is drawn to a polynucleotide encoding a polypeptide of SEQ ID NO: 10, classified in class 435, subclass 69.1, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups (I to VI), (VII to VIII) and (XI to XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, antibodies that are Inventions I to VI, polypeptides that are Inventions VII to VIII and polynucleotides that are Inventions XI to XII are all independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has independent utility that is distinct for each invention which cannot be exchanged. Each of these products are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art chemical compounds. Because these products are structurally distinct molecules, the search of each of these products is not coextensive. In cases as this one where descriptive sequence information is provided, the sequences are searched in

appropriate databases. There is search burden also in the non-patent literature as well as in electronic databases. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature.

3. The polypeptide of Group (VII to VIII) and polynucleotide of Group (XI to XII) are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group (XI to XII) does not necessarily encode the polypeptide of Group (VII to VIII). Furthermore, the information provided by the polynucleotide of Group (XI to XII) can be used to make a materially different polypeptide than that of Group (VII to VIII). In addition, while a polypeptide of Group (VII to VIII) can be made by methods of using some, but not all, of the polynucleotides that fall within the scope of Group (XI to XII), it can also be recovered from a natural source using biochemical means, such as affinity chromatography, for example.

Furthermore, searching the inventions of Groups (VII to VIII) and (XI to XII) together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of Groups (VII to VIII) and (XI to XII) have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search

burden in the non-patent literature and electronic databases. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, the scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above. As such, it would be burdensome to search the inventions of Groups (VII to VIII) and (XI to XII).

4. The polypeptides of Group (VII to VIII) and the antibodies of Group (I to VI) are patentably distinct for the following reasons: while the inventions of both Groups (VII to VIII) and (I to VI) are polypeptides, in this instance, the polypeptides of Group (VII to VIII) is a single chain molecule of ROBO protein, whereas the polypeptide of Group (I to VI) encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptides of Group (VII to VIII) and the antibodies of Group (I to VI) are structurally distinct molecules; any relationship between a polypeptide of Group (VII to VIII) and an antibody of Group (I to VI) is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptides of Group (VII to VIII) are structurally unrelated large molecules which contain potentially hundreds of regions to which an antibody can bind, whereas the antibody of Group (I to VI) is defined in terms of its binding specificity

to a small structure within the disclosed SEQ ID NO. Thus, immunization with the polypeptide of Group (VII to VIII) would result in the production of antibodies outside the scope of Group (I to VI). Furthermore, searching the inventions of Group (VII to VIII) and Groups (I to VI) would impose a serious search burden because both groups require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search would not necessarily determine novelty and unobviousness of the antibodies. Furthermore, antibodies which bind to an epitope of a polypeptide of Group (VII to VIII) may be known even if a polypeptide of Group (VII to VIII) is novel. In addition, the technical literature search for the polypeptides of Group (VII to VIII) and the antibodies of Group (I to VI) is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

5. The polynucleotide of Group (XI to XII) and the antibody of Group (I to VI) are patentably distinct for the following reasons: the antibody of Group (I to VI) includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of Group (I to VI) which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group (XI to XII) will not encode an antibody of Group (I to VI), and an antibody of Group (I to

VI) cannot be encoded by a polynucleotide of Group (XI to XII). Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups (XI to XII) and (I to VI) would impose a serious search burden since a search of the polynucleotide of Group (XI to XII) would not be used to determine the patentability of an antibody of Group (I to VI) and vice-versa.

6. Inventions (VII to VIII) and (IX to X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptides of Group (VII to VIII) could be used in an entirely different manner such as for the production of antibodies as opposed to its use in the methods of Groups (IX to X).

Searching for the inventions of Groups (VII to VIII) and (IX to X) together would impose a serious search burden. The inventions of Groups (VII to VIII) and (IX to X) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of (IX to X) using a polypeptide are not coextensive. Group (VII to VIII) encompasses molecules, which are claimed in terms of fragments of polypeptides of SEQ ID NO: 8 and 10, which are not required for the search of Group (IX to X). In contrast, the search for Group (IX to X) would require a text search for the method of testing a compound that affects cellular signaling response in addition to a search for SEQ ID NO: 8 or 10. Prior art, which

teaches a polypeptide which is a fragment of a polypeptide of SEQ ID NO: 8 or 10 would not necessarily be applicable to the method of using the polypeptide comprising SEQ ID NO: 8 or 10. Moreover, even if polypeptide product were known, the method, which uses the product may be novel and unobvious in view of the preamble or active steps.

7. Inventions (I to VI and XI to XII) and (IX to X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because the product of Groups (I to VI and XI to XII) is not used or otherwise involved in the process of Group IX or X.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, which also includes searching different electronic databases, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. This application contains claims directed to the following patentably distinct species: different fragments of a polypeptide of SEQ ID NO: 8 and SEQ ID NO: 10. The species are independent or distinct because these fragments represent different non-

overlapping peptides, which can be embedded within polypeptides not limited to the polypeptide of SEQ ID NO: 8 and 10, and for which an individual sequence search must be performed.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10 and 24 generic.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

October 27, 2006